REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The amendment to the claims further defines what the applicant regards as the invention. Full support for the amendment, including new claims 60 and 61, can be found throughout the present application, including the claims as originally filed, for instance, in claims 2, 12, and in Figures 4-6 of the present application. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Claims 1-11, 13-38, and 40-61 are pending in the application. Claims 12, 39, 41, and 47 have been canceled. Claims 40, 42-46, 48, and 49 have been withdrawn.

At page 2 of the Office Action, the Examiner has acknowledged that claims 40, 42-46, 48, and 49 have been withdrawn as the result of a restriction requirement. New claims 60 and 61 are indirectly dependent on claim 1, and are therefore part of the elected invention.

At page 2 of the Office Action, the Examiner provides the reasons for the Restriction Requirement. The Applicants affirm the election of Group II. The Applicants believe that the subject matter of Group I can be examined as well at this time. At a minimum, Group II should be rejoined upon allowance of the elected claims.

At page 3 of the Office Action, the Examiner objects to claim 39 as being substantially duplicative of claim 38. For the following reasons, this objection is respectfully traversed.

Claim 39 has been canceled. Accordingly, this objection should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 16-18 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which the applicant regards as the invention. More specifically, the Examiner states that a recitation of zirconium phosphate (ZrP) in claim 16 does not include a proper antecedent basis. For the following reasons, this rejection is respectfully traversed.

Proper antecedent basis has been made for claim 16. The scope of claim 16 remains the same. Accordingly, this rejection should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 1, 2, 11, 12, 19, 21, 29, 30, and 50-57 under 35 U.S.C. §102(b) as being clearly anticipated by Polak et al. (U.S. Patent No. 4,650,587). According to the Examiner, Polak et al., at column 5, line 68 - column 6, line 11, describes a sorbent cartridge having at least one sodium zirconium carbonate (SZC) as recited in claims 1 and 11 of the present application. Furthermore, the Examiner asserts that Polak et al. illustrates an absorbent as a layer as recited in claims 2 and 12 of the present application. Additionally, the Examiner states that Polak et al., at column 6, lines 1-9, describes the composition of the SZC as recited in claim 19 of the present application. The Examiner acknowledges that the LOD of 30-40% is not described in Polak et al. However, the Examiner believes that water-loss from drying SZC is an inherent material property. The Examiner also concludes that Polak et al. describes the SZC as recited in claim 21 of the present application. The Examiner asserts that Polak et al. teaches an apparatus for conducting dialysis wherein the sorbent cartridge is in fluid communication with a dialyzer as in claim 50 of the present application. According to the Examiner, the dialysis fluid could be spent hemo-dialysis fluid, and could be restored to the original Na^+ and HCO^{3-} content as recited in claims 51, 52, 54, and 57 of the present application. The Examiner also states that the apparatus of Polak et al. could be in communication with the blood of a patient as recited in claim 53 of the present application. Additionally, the Examiner asserts that

Polak et al., at column 5, lines 60-68 and column 2, lines 25-40, describes the peritoneal dialysis as recited in claims 55 and 56 of the present application.

With respect to claims 29 and 30 of the present application, the Examiner states that according to case law, discovery of an optimum value of a result effective variable in a known process is within the skill of the art. For the following reasons, this rejection is respectfully traversed.

The claimed invention relates to a sorbent cartridge comprising at least one SZC, wherein the SZC is present as a layer in the sorbent cartridge. Furthermore, the claimed invention relates to a sorbent cartridge including an alkali metal-Group IV B metal carbonate, wherein the alkali metal-Group IV B metal carbonate is present as a layer in the sorbent cartridge.

Polak et al. relates to a particulate magnesium phosphate product (MGP) and to a method for removing ammonia from aqueous solutions. According to Polak et al., the magnesium phosphate product can be utilized as a replacement for ZrP materials used to remove ammonia produced by enzymatic hydrolysis of urea in recirculating dialysis systems utilizing disposable cartridges. Therefore, contrary to the Examiner's statements, Polak et al. never teaches or suggests using a layered structure and never once teaches ZrP with SZC. Columns 5 and 6 of Polak et al., which the Examiner relies upon, only shows MGP with SZC. Polak et al. does not teach or suggest that the SZC is present as a layer in a sorbent cartridge. See Figure 2 and column 6, lines 9-11. Polak et al. only describes a mixture of MGP and SZC components in a pouch. Moreover, Polak et al. uses magnesium phosphate with a SZC and discourages the use of ZrP. There is no teaching in Polak et al. to use ZrP with SZC.

In one embodiment of the present application, the SZC layer is, in part, a phosphate

adsorbent, which can remove phosphate from a renal disease patient for the treatment of hyperphosphatemia. Preferably, SZC produces bicarbonates, which can be delivered to a patient for correcting the metabolic acidosis. Furthermore, the SZC layer preferably buffers the acidity of the dialysate caused by the lattice hydrogen ions of ZrP and hydrous zirconium oxide (HZO), which will otherwise decompose the bicarbonate dialysate and lower the bicarbonate level of the patient.

Finally, the layer structure of the claimed invention is based on the principle of adsorption column design to ensure high adsorption efficiency. A blended mixture of components, especially a blended mixture of ZrP and SZC, will not only cause a high level of phosphate leakage, but also can cause a rapid uncontrolled reaction, which produces CO_2 gas during application.

Accordingly, this rejection should be withdrawn.

At page 6 of the Office Action, the Examiner rejects claims 20, 38, and 39 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. The Examiner asserts that Polak et al. describes the limitations of claim 1, but does not specify whether the SZC satisfies the ANSI/AAMI. However, the Examiner states that it would be obvious to one of ordinary skill in the art, at the time the invention was made, that the same material would also satisfy the same requirement. With respect to claims 38 and 39, the Examiner acknowledges that the added limitation of two or more layers of absorbents in the cartridge is not taught by Polak et al. However, the Examiner states that it would be obvious to one of ordinary skill in the art, at the time the invention was made, to have the absorbents in a separately layered structure in the cartridge as a way for structuring the cartridge. For the following reasons, this rejection is respectfully traversed.

Polak et al. does not teach or suggest one function of the SZC, which is to generate bicarbonate in dialysate to buffer the solution. Polak et al. also does not describe the generation of bicarbonate in dialysate because such a function is accomplished preferably by the layered structure of the cartridge, which is not taught by Polak et al. As stated, Polak et al. only shows a mixture of MGP and SZC components in a pouch. The Examiner has no basis to disregard the clear teachings of Polak et al. and take the unsupported position that a layered structure that includes SZC would be obvious. Only hindsight can create this conclusion. Also, the ANSI/AAMI parameters are not automatically met by any use of SZC. This is especially true when minor amounts of SZC are being used in Polak et al., and MGP is the primary component. The present invention provides means to achieve these parameters, wherein Polak et al. does not. The Examiner is incorrectly speculating about the properties not mentioned in Polak et al. and does not provide any support for these conclusions.

Also, claim 20 is dependent on claim 1. Therefore, the reasons set forth above with respect to the patentability of claim 1 would also apply here. Furthermore, claim 39 is canceled and claim 38 is directly dependent on claim 11. Therefore, the reasons set forth above with respect to the patentability of claim 11 would also apply here. Accordingly, this rejection should be withdrawn.

At page 6 of the Office Action, the Examiner rejects claims 3-9, 13-16, 22-25, 31-37, 58, and 59 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the applicant's own disclosure of prior art. According to the Examiner, Polak et al. describes all of the limitations of claims 1, 11, and 50. The Examiner then asserts that the applicant's disclosure of the REDY cartridge teaches the additional limitations of the instant claims.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art, at

the time the invention was made, to use the teaching of the REDY cartridge in the teaching of Polak et al. as the "zirconium phosphate or its progeny" for purifying the spent dialysate as taught by Polak et al. For the following reasons, this rejection is respectfully traversed.

The REDY cartridge includes layers, whereas the cartridge of Polak et al. does not. How the REDY cartridge can be combinable with Polak et al. is not seen. The features of the claimed invention in these claims are unique in the sense that the features in the claimed invention are based on the combination of the ZrP with SZC wherein the SZC is present as a layer. The SZC layer and the ZrP of the claimed invention preferably function to adjust the Na^+ and bicarbonate of the regenerated dialysate to the right level; therefore, allowing the use of the cartridge for other treatments and a broader range of dialysis conditions. As is mentioned above, Polak et al. describes a mixture of MGP and SZC components in a pouch. However, in the claimed invention, the SZC is used in the form of a layer and ZrP is present to assist in regenerating dialysate to preferred levels. Further, one cannot simply replace the layers in the REDY cartridge with the material of Polak et al. and expect success. At best, this is an improper obvious to try standard. This is especially true when ZrP is not used in Polak et al. and layers are not present. Neither reference provides any teaching, suggestion, or motivation to make such layer substitutions. The Examiner cannot simply pick and choose layers and design a cartridge for a rejection when the prior art does not provide the motivation. The Examiner is improperly using hindsight to make this argument. The REDY disclosure does not suggest such a substitution and Polak et al. certainly does not. For the reasons set forth above, one skilled in the art would not be motivated to combine the teachings of the REDY cartridge with Polak et al. Furthermore, claims 3-9, 13-16, 22-25, 31-37, 58, and 59 are directly or indirectly dependent on claims 1 or 11. Therefore, the reasons set

forth above with respect to the patentability of claim 1 would also apply here. Accordingly, this rejection should be withdrawn.

At page 8 of the Office Action, the Examiner rejects claims 26-28 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of Potts (U.S. Patent No. 5,234,603). According to the Examiner, claims 26-28 of the present application further limit the claimed invention by reciting that the composition of the claimed invention includes a zirconium carbonate and by providing the purity of the zirconium carbonate. The Examiner then asserts that Potts describes a basic zirconium carbonate for removing heavy metals, transition metals, and organic matter from wastewater. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teaching of Potts with the teaching of Polak et al. for removing heavy metals and transition metal ions from the dialysate as taught by Potts. For the following reasons, this rejection is respectfully traversed.

Polak et al. relates to the preparation of magnesium phosphates and their exploitation in the medical field, and their use in recirculating dialysis systems and other systems having the purpose of removing urea/ammonia from bodily fluids and in wastewater treatment to remove ammonium ions. In contrast, according to Potts, at column 3, lines 55-61, the contaminants to be removed include actinide and lanthanide metals, transition metals, heavy metals, suspended solids (either organic, inorganic, and/or biological), alkaline earth metals, and similar insoluble materials (and materials which can be made insoluble) in the wastewater. Potts does not teach or suggest removal of urea or ammonia. Thus, the two references are not within the same field of endeavor. Accordingly, one skilled in the art wanting to learn about removal of urea/ammonia from bodily fluids would not look to Potts. The Examiner cannot use hindsight to mix and match the layers.

Absolutely no suggestion is made in either reference for mixing and matching the layers. Furthermore, claims 26-28 are dependent directly or indirectly on claim 1. Therefore, the reasons set forth above with respect to the patentability of claim 1 would also apply here. Accordingly, this rejection should be withdrawn.

At page 8 of the Office Action, the Examiner rejects claims 26-28 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge and Potts. The Examiner asserts that the REDY cartridge includes ZrO for purifying spent dialysate. Furthermore, the Examiner states that Potts describes a basic zirconium carbonate for removal of heavy metals, transition metals, and organic matter from wastewater, and that zirconium carbonate would hydrolyze to form a polymeric oxide chain. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have the teachings of the REDY cartridge and Potts in the teaching of Polak et al. for purifying the spent dialysate as taught by Polak et al. For the following reasons, this rejection is respectfully traversed.

The arguments set forth above with respect to Polak et al., the REDY cartridge, and Potts apply equally here. Furthermore, claims 26-28 are dependent directly or indirectly on claim 1. Therefore, the reasons set forth above with respect to the patentability of claim 1 apply equally here. Accordingly, this rejection should be withdrawn.

At page 9 of the Office Action, the Examiner rejects claims 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge and further in view of Marantz et al. (U.S. Patent No. 3,669,880). According to the Examiner, claims 17 and 18 of the present application add structural components like filter pads and a diffuser. The Examiner then states that the REDY cartridge includes a filter pad (Fig. 1), but not the diffuser for flow

distribution. However, the Examiner states that Marantz et al. describes a flow distributor and filter pads. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the teaching of Marantz et al. in the teaching of Polak et al. in view of the REDY cartridge for the flow distribution and for preventing the breakup and inter-mixing of particles in layers as taught by Marantz et al. For the following reasons, this rejection is respectfully traversed.

Marantz et al. relates to a recirculating dialysate system for use with an artificial kidney in which the total volume of dialysate solution is controlled. According to Marantz et al., the urea in the solution is removed in a ZrP column containing urease and the other waste products are removed in the carbon column containing activated carbon and hydrated zirconium oxide. In contrast, Polak et al. teaches away from Marantz et al. by replacing the ZrP with magnesium phosphate. Thus, one skilled in the art by reading Polak et al. would conclude that since the composition of Polak et al. is different from Marantz et al., the cartridge used in Marantz et al. would not work in Polak et al. Thus, one skilled in the art would not be motivated to combine Polak et al. and Marantz et al. Furthermore, as discussed earlier, one skilled in the art would also not combine the REDY cartridge with Polak et al. Additionally, claims 17 and 18 are dependent directly or indirectly on claim 1. Therefore, the reasons set forth above with respect to the patentability of claim 1 would also apply here. Accordingly, this rejection should be withdrawn.

At page 9 of the Office Action, the Examiner rejects claim 10 under 35 U.S.C. §103(a) as being unpatentable over Polak et al. in view of the REDY cartridge and further in view of Tawil et al. (U.S. Patent No. 4,025,608). The Examiner asserts that ZrP has an average grain size of from about 30 to about 40 microns, which Polak et al. in view of the REDY cartridge does not teach.

However, the Examiner states that Tawil et al. describes the particle size of the ZrP. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the zirconium oxide particle size of Tawil et al. in the teaching of Polak et al. in view of the REDY cartridge for good flow distribution. For the following reasons, this rejection is respectfully traversed.

Tawil et al. relates to a ZrP that is made by reacting a zirconium salt with a phosphoric acid or a phosphate in a liquid medium, wherein the zirconium salt is insoluble in water. The Examiner cannot simply substitute different particles and argue that the same size automatically can be used. There is no support for such a conclusion. According to Tawil et al. at column 2, lines 54-59, the grain size of the ZrP is at least 30 microns. As discussed above, Polak et al. even teaches away from the use of a ZrP. Thus, one skilled in the art when reading Polak et al. would not be motivated to look to Tawil et al. for any guidance. Furthermore, as stated earlier, one skilled in the art would not combine the teachings of Polak et al. with the REDY cartridge, and even if combined, a mixture of various components, and not layers, would be used. Therefore, one skilled in the art would not be motivated to combine Polak et al. with the REDY cartridge and Tawil et al. to derive claim 10 of the present application. Furthermore, claim 10 is dependent indirectly on claim 1. Therefore, the reasons set forth above with respect to the patentability of claim 1 would apply equally here. Accordingly, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

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